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STATEMENT OF DR. RAYMOND D. HARBISON CONCERNING H.R. 4543 "THE CIGARETTE TESTING AND LIABILITY ACT OF 1988" My name is Raymond,D. Harbison. I am Professor and Director of the Interdisciplinary Toxicology Program at the University of Arkansas for Medical Sciences and I am Board Certified in Toxicology. A copy of my curriculum vitae is attached to this prepared testimony, which I am submitting on behalf of The Tobacco Institute. I appreciate this opportunity to record my views concerning H.R. 4543, the Cigarette Testing and Liability Act of 1988. The purpose of my statement is to describe from a toxicological perspective the utility and relevance of any smoke constituent information that would be elicited by the FTC-arranged studies required under Section 2 of H.R. 4543 -- both on the intrinsic merit of such data, and as that information is likely to be disseminated by labeling or disclosure requirements imposed by States and municipalities under Section 3 of the bill. As described below, I believe that additional constituent disclosure requirements will not be of any informational or health benefit to smokers (or those considering whether or not to smoke). In fact, any such constituent testing and disclosure requirements could mislead consumers and have a detrimental effect on numerous consumer products and industries having nothing to do with tobacco.

STATEMENT OF DR. RAYMOND D. HARBISON
CONCERNING H.R. 4543
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an effort to define its composition and to identify those components which may have adverse effects on human health. This research has been performed both within the cigarette industry and by researchers unaffiliated with the industry. Thus far, over 4,000 constituents of cigarette smoke have been identified. The identity of those constituents is readily available to anyone interested in them. There is no apparent reason, however, why any lay person would be interested in knowing the identities of these constituents or their levels in smoke, because there is no reliable evidence that any one of those constituents can account for the adverse human health effects which have been attributed to smoking. The toxicity of any substance, including a substance which is said to cause cancer, is dependent on its concentration. This is simply a reiteration of the well known maxim that "The poison is in the dose." There are some substances in cigarette smoke -- as well as in a wide variety of foodstuffs and beverages -- which, when applied in enormous quantities, can cause cancer on the skins of some animal species. However, the industry's critics have agreed that the allegedly harmful substances identified in cigarette smoke are present in such minute quantities that they cannot even begin to account for the pathological effects cigarette smoking is said to produce.

-2-

I. The History of Smoke Constituent Testing

Researchers have been analyzing cigarette smoke for many years in an effort to define its composition and to identify those components which may have adverse effects on human health. This research has been performed both within the cigarette industry and by researchers unaffiliated with the industry. Thus far, over 4,000 constituents of cigarette smoke have been identified. The identity of those constituents is readily available to anyone interested in them.

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paper clip. In order to discuss the constituents of smoke, it is necessary to move to the milligram range and below. A milligram is extraordinarily small, being only one-thousandth of a gram. "Tar" and nicotine contents are measured in the very low milligram range. There are typically about 500 milligrams of mainstream smoke in a cigarette. Of that amount, 435 milligrams (over 80%) is composed of carbon dioxide, water, nitrogen and oxygen. The other 4,000 or so identified constituents comprise only about 65 milligrams, or less than 20% of the mainstream smoke. Not surprisingly, almost all of these constituents are found in the microgram (one-millionth of a gram) or nanogram (one-billionth of a gram) range. (By illustration, one nanogram as a weight relative to one gram is the equivalent, in time, of one second every 31.7 years.) Given current testing, identification and instrumentation capabilities, any as-yet unidentified constituents must be found in even smaller quantities. As we all know, researchers have from time to time advanced theories as to the identities of the particular constituent or constituents of smoke responsible for disease; in each instance, either those same researchers or other competent authorities equally convinced of the adverse health effects of smoking, have studied the evidence and rebuffed the

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A standard American cigarette contains a little less than one gram of tobacco -- the approximate weight of a paper clip. In order to discuss the constituents of smoke, it is necessary to move to the milligram range and below. A milligram is extraordinarily small, being only one-thousandth of a gram. "Tar" and nicotine contents are measured in the very low milligram range.

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An example of the problems associated with this effort is the case ~ of benzo[a]pyrene. In the mid-1950's, soon after the first- retrospective studies associated smoking and lung cancer, a number of scientists alleged that benzo[a]pyrene [BAP], a polycyclic aromatic hydrocarbon which is a product of incomplete combustion of many organic materials, and which is present in cigarette smoke to the extent of about 10 to 50 nanograms per cigarette, was causing the lung cancer in smokers. It was not long, however, before that theory, too, fell by the wayside. By 1955, Dr. Ernst Wynder, a prominent anti-tobacco scientist, wrote: We feel that as yet unestablished carcinogens or co-carcinogens are in tobacco tar, since the concentration in which benzpyrene seems to be in cigarette tar is insufficient to account for the observed carcinogenic activity to mouse epidermis [of cigarette smoke condensate]. Wynder, E.L. and Wright, G.H., "Fractionation of Cigarette Tar," Proc. Am. Assn. Canc. Research 2(1): 55, 1955. By 1957, Dr. Wynder reported: The benzpyrene content of cigarette tar is not more than 2 ppm., which, according to our experiments, is not sufficient to produce the type of activity noted in our animals painted with tobacco tar. Wynder, E.L., "Towards a Solution of the Tobacco-Cancer ~ ~ (1) pp 1-3 " Brit Journal 1957 Problem Med , , ~ ~ Llt U1 Ld W

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proposed theory. Scientists nevertheless continue to look for the "cause" of disease in the constituents of smoke. An example of the problems associated with this effort is the case of benzo[a]pyrene.

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human exposure, no tumors at all were produced: Cigarette tar, used in this study contained between 1 and 2 ppm of benzpyrene. One does not know what level of continued exposure may be carcinogenic to man. We have demonstrated experimentally . . . that 0.0001 percent or even 0.0005 percent benzpyrene in acetone will not produce any tumors in the present experimental mouse or rabbit groups. Wynder, E.L., Fritz, L., and Furth, N., Effect of Concentration of Benzopyrene in Skin Carcinogenesis, J. NATL. CANCER INST., 19, 361-370 (1957). These solutions [0.0001% (1 microgram/ml) and 0.0005% (5 microgram/ml)] used in the daily skin painting in these studies are equivalent to the BAP in the cigarette smoke condensate from about 50 and 250 cigarettes, respectively -- i.e., the equivalent of about 2.5 to 12.5 packs per day if the cigarette smoke condensate from one cigarette contains 20 nanograms of benzo[a]pyrene. In 1966, Lazar and others reported, in the Journal of the National Cancer Institute, that increasing BAP content of cigarette mainstream smoke by as much as 30 times gave no increase in carcinogenic activity on mouse skin. They concluded: The Benzo(a)pyrene content is not important in the carcinogenicity of cigarette smoke. Lazar, P., et al., "Benzo[a]pyrene Content and Carcinogenicity of Cigarette Smoke Condensate -- Results of Short-Term and Long-Term Tests," Journal of the National Cancer Institute Vol. 37: 1966, pp. 573-579.

-5-

Also in 1957, Dr. Wynder reported that if tar was applied to animals at levels which might conceivably occur in human exposure, no tumors at all were produced:

Cigarette tar, used in this study contained between 1 and 2 ppm of benzpyrene. One does not know what level of continued exposure may be carcinogenic to man. We have demonstrated experimentally . . . that 0.0001 percent or even 0.0005 percent benzpyrene in acetone will not produce any tumors in the present experimental mouse or rabbit groups.

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inhaled amount of BAP equivalent to the BAP in 715 cigarettes per day -- i.e., more than 35 packs per day. These roofers had no increased incidence of lung cancer: Even if all the men studied had been nonsmokers (which they were not) and worked only one day a week, they still would have inhaled at least as much BAP per year as very heavy cigarette smokers in the general population. Hammond, E.C., Selikoff, I.J., and Lawther, P.J., "Inhalation of Benzpyrene and Cancer.in Man," Paper presented at American College of Chest Physicians, Chicago, Il., October 30, 1969. Based on this report, the American Cancer Society admitted: A known cancer causing agent in experimental animals might have to be ruled out as a cause of lung cancer in man. The American Cancer Society News Service 2, New York, October 31, 1969. Of course, it is well known that benzo[a]pyrene is commonly found in browned and carmelized foods, such as bread crusts and cakes, in roasted coffee, and in smoked and charcoal broiled foods. For example, two researchers reported in Science that the amount of BAP found in a single charcoal broiled steak was about the same as that measured in the smoke of 600 cigarettes -- three full cartons. Lijinsky, W. and Shubik, P., Benzo[a]pyrene and Other Polynuclear Hydrocarbons in Charcoal-Broiled Meat. SCIENCE, 145, 53 (1964). Dansi, A. and Zanini, C., Practical Meaning of the Polycyclic Hydrocarbons in Roasted Coffee. TUMORI, 45, 65-70 (1959).

-6-

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Roasted Barley, Shoyu, and Caramel, GANN, 57, 133 (1965). Following the isolation of BAP from cigarette smoke, researchers sought to identify other polycyclic aromatic hydrocarbons (PAH's) which might be causing a carcinogenic effect. However, most of the other PAH's were present in even smaller concentrations than BAP, some even in the picogram range, one thousand times smaller than a nanogram. (Using again the time reference, a picogram, being one-thousandth of a of nanogram, is equivalent in time to one second in 31,700 years.) Their presence was not significant enough to cause anyone to conclude the PAH's were the problem. In 1981, the Surgeon General concluded that the evidence regarding benzo(a)pyrene and PAH's was, at best, equivocal: The contribution of BAP, or PAH's in general, to mouse skin carcinogenesis by cigarette smoke condensate cannot be fully measured at this time. Wynder and Hoffmann found a correlation between BAP levels and carcinogenic activity of smoke condensates from several types of cigarettes. A much larger series of experimental cigarettes was studied in the smoking and health program of the National Cancer Institute. No significant dependence of carcinogenic potency on BAP content was observed. 1981 Surgeon General's Report, at 36, 59. The experience with BAP has many counterparts in the cases of other cigarette smoke constituents which at one time or another were authoritatively -- but erroneously -- claimed to be the "cause" of disease. If scientists whose goal was to

-7-

Masudo, Y., Mori, K., and Kuratsune, M., Polycyclic Hydrocarbons in Common Japanese Foods. I. Broiled Fish, Roasted Barley, Shoyu, and Caramel, GANN, 57, 133 (1965).

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public can benefit from additional constituent information, the significance of which is not readily apparent. It should also be noted that if the constituents which are being investigated are in the "tar" phase, their relative concentrations are generally reflected by the FTC "tar" value. In addition, the various carbon monoxide values approximate the relative concentrations of other gas phase constituents.

II. The Importance of Having Information That Is Useful to the Consumer

My conclusion that it is undesirable to require a massive new Federal effort to identify additional smoke constituents, and to re-confirm the existence of those already identified, does not rest solely on the ground that the effort is unlikely to result in the identification of harmful compounds. I also believe that the additional testing required by H.R. 4543 will not provide consumers with any meaningful toxicological data but will instead mislead them in several respects. While we have identified smoke constituents down to minute quantities, in 30 years no credible evidence has established that any one of these 4,000 compounds poses a human health problem at the concentrations found in smoke. And while additional constituents will likely continue to be identified, they will be present in such small quantities -- particularly

-8-

isolate and identify harmful constituents have not been successful, it seems extraordinarily unlikely that the lay public can benefit from additional constituent information, the significance of which is not readily apparent. It should also be noted that if the constituents which are being investigated are in the "tar" phase, their relative concentrations are generally reflected by the FTC "tar" value. In addition, the various carbon monoxide values approximate the relative concentrations of other gas phase constituents.

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and water supply -- that as a toxicologist, I view it as extraordinarily unlikely that any one of them will be found at a dose sufficient to be a cause of human disease. This does not rule out the possibility that some or all of the constituents, acting together, occasion disease. It does, however, suggest that a more effective use of resources would be to test whole smoke, and attempt to understand the biological mechanisms underlying the diseases associated with whole smoke, rather than attempting to identify compounds which are present in ever more miniscule concentrations in smoke. Congress should exercise caution in considering whether to mandate disclosure of specific constituents in cigarette smoke, lest wholesale public confusion result. Cranberries in the 1960's and bacon and other preserved foods in the 1970's are just two examples of products that were the subject of widespread -- and later shown to be unfounded -- consumer fears. Presumably Congress has no interest in fostering similar consumer purchasing gyrations in the tobacco industry, even if it is convinced that smoking is undesirable. Yet that, I predict, may well occur as a result of the reporting mandated by H.R. 4543. constituent Brand-specific reporting of the amounts of various constituents would imply, contrary to fact, that consumers were

-9-

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however, it would merely invite irrational speculation that would inevitably spill over into products and industries unrelated to cigarettes. Furthermore, people encounter most, if not all of the compounds found in cigarette smoke from numerous other sources as well, often in vastly greater quantities. Since smoke constituents are encountered everywhere, it is inherently misleading to inform the public that cigarettes contain so much cyanide, or benzo[a]pyrene, or ammonia, for example, without also informing the public that these constituents are also found in other places. For example, water contains cyanide, toast and many other foodstuffs contain benzo[a]pyrene and ammonia is encountered everywhere. Not to report these facts is both to impose the whole burden of public concern on the cigarette industry -- a concern that derives, in turn, solely from the fact that the government is reporting the existence of these compounds, and not from any scientific evidence -- and to imply, incorrectly, that non-smokers do not come into contact with these compounds. The likely result of the enactment of H.R. 4543 would be an annual rash of completely unwarranted public concern about many of the compounds that are found, not just in tobacco smoke, but in the water we drink, the food we eat, and the air we breathe. Many people chose to smoke. There is epidemiological evidence that that choice entails risk, and as a toxicologist I

-10-

being given meaningful information and that the reported levels had some health significance. In truth, however, it would merely invite irrational speculation that would inevitably spill over into products and industries unrelated to cigarettes. Furthermore, people encounter most, if not all of the compounds found in cigarette smoke from numerous other sources as well, often in vastly greater quantities.

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